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### **REMARKS**

Initially, Applicants thank the Examiner for the courtesies extended during the interview of November 22, 2004, and for the Examiner's diligence with respect to providing the Interview Summary dated November 26, 2004. Applicants request that the Examiner carefully consider the foregoing amendments in light of the comments made during the interview and the remarks which follow.

Claims 1-69 are all the claims pending in the present application, claims 41-57 having been withdrawn from consideration by the Examiner. While Applicants are mindful of the Examiner's position detailed in the discussion at page 6, of the outstanding Office Action dated September 13, 2004, Applicants respectfully request reconsideration of the requirement in view of the discussion during the interview and the foregoing amendments. Accordingly, and as set forth in the provisions of 37 C.F.R. § 1.143, Applicants reconfirm the provisional election of claims 1-40 and 58-69 (*i.e.*, Group I as defined by the Examiner), but respectfully request reconsideration and withdrawal of the restriction requirement as set forth below.

Applicants intend to address the provisional double patenting rejection set forth at page 2 of the outstanding Office Action when the Examiner indicates that allowable subject matter has been recited in the present application.

Claims 1, 13, 20, 34, 41, 49, and 58 have been amended to recite aspects of the disclosed embodiments with more particularity. Support for the foregoing amendments is found throughout the present application, and in particular in the discussion beginning at page 32, line 12, and continuing to page 33, line 27. No new matter has been added.

As set forth in the outstanding Office Action, claims 17-19, 38-40, and 68 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Claims 1-40 and 58-69 stand rejected under 35 U.S.C. § 102(e) as anticipated by WO 01/31333 A1 to Milosavijevic et al. ("the '333 publication"). Claims 1-14, 20-35, 58-66, and 69 stand rejected under 35 U.S.C. § 102(e) as anticipated by WO 01/31317 A1 to Hogan et al. ("the '317 publication"). Additionally, claims 15-19, 36-40, 67, and 68 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the '317 publication.

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Applicants address the definiteness of the claims and traverse the prior art rejection as set forth below; Applicants respectfully request reconsideration and allowance of all the pending claims in light of the following remarks.

Aspects of the present invention relate generally to a system and method of archiving and retrieving biological or non-biological samples maintained in desiccated form at a plurality of sample nodes on a carrier. Each "node" is a unitary structural element operative to maintain, carry, or otherwise to support a discrete sample as addressed, among other places, in the description of FIGS. 5A-5E beginning at page 31, line 24, and continuing to page 39, line 25, of the present application.

## The Interview Summary

Initially, Applicants address the Examiner's characterization of a "node" as evidenced in the outstanding Office Action and as succinctly articulated in the Interview Summary. As discussed during the interview, the Examiner has attempted to read the term "node" as encompassing an individual well in a microwell plate (microtiter plate) or even an individual test tube. Applicants submit that a "node" as described in the present application and as recited in the pending claims can be read neither on a well in a microwell plate, nor on any other such container, at least for the reasons provided below.

The pending application draws clear distinctions between a "node," on the one hand, and a container, test tube, or well in a microwell plate, on the other hand. As set forth in the discussion bridging pages 28 and 31 (with specific reference to FIGS. 4A-4C) of the specification, a "node" as recited in the pending claims is described as a discrete or unitary structural entity that is entirely distinct from any sort of container into which the "node" is, or may be, deposited. In that regard, a "node," as a unitary structural entity, is still a node, irrespective of its location (whether deposited in a well of a microwell plate or not). Similarly, a container or a well in a microwell plate is not a "node," irrespective of the nature of its contents at any particular moment in time, at least for the following reasons.

In the paragraph bridging pages 32 and 33 of the present application, the specification explains that a sample "node" generally comprises "a sample support medium . . [which] may be embodied in paper or cellulose, polystyrene, plastic, or other suitable support material constructed and operative to serve as a long-term storage mechanism for biological or other samples in a desiccated form." As described and claimed in the present application, a "node" is

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a material or structural entity, and not simply a container into which such a structure may be deposited. Similarly, a "support medium" is a non-fluid structural element, and not simply a buffer or other reagent with which liquid sample material may be mixed.

As noted in the passage cited above, a "node" and its associated "support medium" are generally operative to serve as a long-term storage mechanism for "samples in a desiccated form," which generally refers to a dry state as set forth, among other places, at page 44, line 12, of the specification. Such structural elements of a "node," calling out a dry sample carried by a non-fluid support medium, are readily distinguishable from a container. Accordingly, Applicants respectfully disagree with the Examiner's conclusion in the outstanding Office Action, and reiterate the position articulated during the interview that the prior art of record neither teaches nor suggested the nodes recited in the pending claims.

### The Restriction Requirement

Applicants respectfully submit that the Examiner cannot perform an adequate search of the art relevant to Group I without also searching art relevant to Group II, especially given the substance of the interview of November 22, 2004, and the foregoing amendments. It is hoped that, given a more complete understanding of the terms employed in the pending claims, the Examiner will agree that a substantive examination of Group II claims will neither necessitate an additional search nor represent an undue burden on the Office.

Based at least upon the foregoing, Applicants request reconsideration and withdrawal of the restriction requirement in accordance with 37 C.F.R. § 1.143.

### The Rejection Under 35 U.S.C. § 112

As noted above, claims 17-19, 38-40, and 68 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Applicants respectfully submit that the foregoing amendments render clear what structure is derivatized, and that an ordinarily skilled artisan, having read the specification in conjunction with an examination of the drawing figures, would readily be able to understand the recitations of these claims. Accordingly, Applicants request that the rejection under 35 U.S.C. § 112 be withdrawn.

# The Rejections Under 35 U.S.C. § 102(e)

As noted above, claims 1-40 and 58-69 stand rejected under 35 U.S.C. § 102(e) as anticipated by the '333 publication, and claims 1-14, 20-35, 58-66, and 69 additionally stand rejected under 35 U.S.C. § 102(e) as anticipated by the '317 publication. In order to anticipate a

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pending claim under any of the various subsections of 35 U.S.C. § 102, a reference must teach every element recited in the claim. As discussed during the interview and as set forth below, the fair teachings of the asserted publications are insufficient to anticipate the pending claims, and the rejections under 35 U.S.C. § 102(e) are therefore improper.

The cited publications are directed particularly to "punch card" systems as described in the present application in the discussion beginning at page 2, line 10, and continuing to page 3, line 11. See, e.g., the descriptions at page 18, lines 6-11, of the '313 publication, and at page 4, lines 5-18, of the '317 publication. In accordance with the techniques taught in the cited publications, sample material is blotted onto a punch card substrate (designated by reference numeral 24 in FIG. 2) and diffuses through the substrate; this creates a universal or omnibus sample distributed across the substrate. A pellet or plug (designated by reference numeral 100 in FIG. 2) may be punched from anywhere on the substrate, irrespective of the uniformity of the sample material's diffusion, at a later time.

In contrast to the fair teachings of the cited publications, however, each sample node described and claimed in the present application is operative to carry a "discrete" sample. In that regard, the present application does not specifically define the term "discrete" to mean anything more narrow than its ordinary usage suggests: *i.e.*, "separate" or "distinct." The punch card system taught in the cited publications must sever or excise a bit of sample material from an otherwise unified or consolidated substrate, and does not contemplate discrete samples as described and claimed in present application. The Examiner has identified this deficiency in the "317 publication as set forth on page 4 of the outstanding Office Action (acknowledging that the punch head assembly "punches out *a portion* of *the sample*"). Accordingly, a plug punched from a punch card, failing to carry a "discrete" sample as described and claimed in the present application, is not equivalent to a "node" as recited in the pending claims.

Even assuming, arguendo, that the Examiner attempts to read the term "node" broadly enough to encompass such a plug after it has been removed from the substrate, Applicants note that the cited publications still fail to teach or even to suggest a structural array to which the node is attached before such removal. Additionally, the substrate itself is not equivalent to the claimed nodes, at least for the following reasons. As set forth in the present specification in, among other places, the discussion at page 32, lines 1-18, a structural array "generally comprises a plurality of sample structures" which in turn are generally "maintained in a predetermined

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spatial relationship" and are operative to support sample nodes. The substrate disclosed in the cited publications neither includes such "sample structures" nor do the publications contemplate supporting nodes in a "predetermined spatial arrangement." It is understandable that the cited publications are silent in this regard--since the sample material in the punch card system is distributed across the substrate, a plug may be removed from any location on the substrate.

Applicants submit that the cited publications fail to teach or to suggest at least the foregoing structural elements recited in every independent claim (claims 1, 20, 41, 49, and 58). Accordingly, the cited publications are insufficient to anticipate any of the pending independent claims (including those withdrawn from consideration by the Examiner), and the rejections of claims 1-40 and 58-69 under 35 U.S.C. § 102(e) are therefore improper. At least for the reasons set forth above with specific reference to independent claims 1, 20, and 58, their respective dependencies are also allowable. Further, claims 2-19, 21-40, and 59-69 recite additional features and combinations of elements, and Applicants submit that these claims are additionally allowable for their respective recitations as well.

# The Rejections Under 35 U.S.C. § 103

As noted above, claims 15-19, 36-40, 67, and 68 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the '317 publication. Given the clear deficiencies of the '317 publication noted above, however, Applicants respectfully submit that the Examiner's observations (at page 5 of the Office Action) regarding polymers, result effective variables, choice of surface derivatization, and charges, even if true, are not especially remarkable.

In particular, MPEP § 706.02(j) specifies that, in order for the Examiner to establish a *prima facie* case of obviousness, among other criteria, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." Because the cited publications fail to teach every limitation recited in the independent claims as set forth in detail above, the Examiner has failed to establish a *prima face* case of obviousness, and the rejection under 35 U.S.C. § 103(a) is improper.

Accordingly, Applicants submit that the cited publications are insufficient to render obvious any of the pending claims, and request that the rejection of claims 15-19, 36-40, 67, and 68 under 35 U.S.C. § 103(a) be withdrawn.

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#### **CONCLUSION**

Based at least upon the foregoing Remarks, Applicants respectfully submit that all the pending claims (including those withdrawn by the Examiner) are allowable, and that the present application is currently in condition for allowance. The Examiner is encouraged to contact the undersigned at 858-509-4007 if it is believed that a discussion may advance the prosecution of this case.

Applicants believe that a fee is required at this time. Please apply any charges or credit any overpayments to Deposit Account No. 50-2212.

Respectfully submitted,

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#### CERTIFICATION UNDER 37 C.F.R. §§ 1.8 and/or 1.10\*

(When using Express Mail, the Express Mail label number is mandatory; Express Mail certification is optional.)

I hereby certify that, on the date shown below, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Signature

Date: January 11, 2005

**PATRICIA MUNOZ** 

(type or print name of person certifying)

<sup>\*</sup> Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.